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"A test device with a test strip and a lid-provided pretreatment portion"
(Testiväline, jossa on testiliuska ja kannella varustettu esikäsittelyalue)

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A TEST DEVICE WITH A TEST STRIP AND A LID-PROVIDED PRETREATMENT PORTION

The Technical Field of the Invention

The present invention is related to a test device with a lid-provided pretreatment portion mounted on the same backing support as a test strip as well as an improved method for directly carrying out assays from samples generally requiring more or less time consuming pretreatment procedures.

The Background of the Invention

Some biological samples, especially such samples which are taken for making diagnoses from whole blood, serum, urine, feces, saliva, sputum, synovial fluid, etc require pretreatment procedures including removal of particles, agglutination, chemical treatments, release of specific components, immunocapture, etc.

Usually, before carrying out the test, a whole blood sample is coagulated and centrifuged in order to remove blood cells and other interfering or disturbing factors. Many novel and rapid bed-side tests have been developed and they would be perfect for making rapid bed-side tests in emergency situations in ambulances and in hospitals during chirurgical operations. However, the centrifugation is a retarding factor which hampers the use of said tests in really critical situations. Many systems for removing blood corpuscles on a test strip or test device have also been disclosed previously.

The problem connected with said known methods and device is that only one filtering pad is generally not sufficient to retain all blood cells. Another problem, in the known system is that all interfering factors are not retained or redundant fluid might pass the edges of the filtering means.

Thus, the objective of the present invention is to provide a test device for emergency situations, especially for use in ambulances wherein coagulation and centrifugation is not possible to carry or in which said steps are too time consuming. On the test device of the present invention even complicated immunological analysis can be performed rapidly with great accuracy without pretreatment of the sample and furthermore the test device can be modified to meet the requirements in multitude of different test methods.

The Summary of the Invention

The characteristics of the analytical test device with a closed pretreatment system assembled with a test strip are defined in the claims.

A Brief Description of the Drawings

Fig. 1 is a side view of a lid-provided backing support (1) with its edge (1) seen from its inside and the lid (2) snapped in place to protect the layers in the pretreatment system.

Fig. 2 is a schematic picture of the test device with a closed lid (2) snapped on the backing support (1) and with the pretreatment layers (4) (not seen) and the test strip (5) fixed in their correct positions. In the lid (2) is a shaped aperture (3) into which the sample solution and possible diluent or driving solutions can be added.

Fig. 3 is a sectional side-view of the lid-provided backing support (1) with the lid (2) open, the aperture (3) for adding sample solution is seen as an intersection and two pretreatment layers (4) and the test strip (5) are schematically shown.

Fig. 4 is a view seen from above of the lid-provided backing support (1) with the lid (2) open and the aperture (3) shown as dot and with the pretreatment layers (4) and the test strip

(5) placed in their correct positions.

Fig. 5 is a sectional side view of the lid-provided backing support (1) with the lid (2) snapped on the backing support (1) and covering and protecting the layers in the pretreatment system and in capillary flow connection with the test strip, all placed in their correct positions.

Fig. 6 is a sectional view seen from above with a transparent closed lid (2) snapped on the backing support (1). Due to the transparency the lid-covered pretreatment layers (4) can be seen in their correct positions and in capillary flow connection with the test strip (5). The aperture (3) is not shown in this figure.

Fig. 7 is a sectional side view of the lid-provided backing support (1) with the lid (2) open and without pretreatment layers and test strip. In the figure the means including tabs (7) and ribs (7) for securing and fixing the positions of the layers (not shown) in the pretreatment zone or region and test strips (not shown).

Fig. 8 is a schematic picture viewed from above of the lid-provided backing support (1) with the lid (2) open without pretreatment layers (4) and test strip (5). The taps (7) and ribs (7) are shown as well as the side wall protrusions or flanking supports (8) and the area forming the compartment (6) acting as a reservoir for the excess sample fluid.

Fig. 9 is a sectional side view of the lid-provided backing support (1) with the lid (2) snapped in place without pretreatment layers and test strip. In this figure the space provided for the layers are clearly indicated.

Fig. 10 is a sectional view seen from above with a transparent closed lid (2) snapped on the backing support and without the pretreatment layers and test strip. The aperture (3) is shown in this figure as well as the taps and the side

wall protrusions forming the supporting flanks (8).

The Detailed Description of the Invention

Definitions

In the description which follows, most terms are used in the same way they are generally used in diagnostics, immunochemistry and biochemistry and enzymology. However, some terms are used in a somewhat different or more extensive way. In order to provide a clearer and more consistent understanding of the specification and claims including the scope to be given such terms, the following definitions are given.

In one preferred embodiment of the present invention the test strip is an immunochromatographic test producible as follows:

A narrow zone of for example a nitrocellulose strip is coated with a monoclonal antibody against a specific component. Coloured or fluorescent latex particles are coated with another antibody against the same component. The coated latex particles are dried on a zone in the middle of a strip of an absorbing polyethylene material or in a layer placed in the pretreatment zone. The diameter of the latex particles are so small that they can flow freely through the pores in both the appropriate pretreatment layers and strip materials. The layers and the test strips are attached on a plastic backing so that they are in a capillary flow contact of the sample liquid to test strip through the appropriate filter layers.

The test strip is however not restricted to such test strips. A multitude of different determinations which require pretreatment of the sample can be used in the present test device including immunoassays as well as enzymatic, chemical or biochemical test strips.

The General Description of the Invention

The objective of the invention is made feasible by providing an analytical test device, comprising a system for pretreating samples before carrying out an immunochromatographic test.

The device is provided with an area, comprising at least two layers stapled upon each other enabling providing means for physical or chemical treatment of the sample. Said area is provided with a cover with means for keeping the layers fixed in a predetermined position with each others and with the test strip.

The cover or lid is optionally loose or attached to the backing support by fastening means such as hinges or pivots. The fastening means can be placed on any side of the backing support, but the most preferable place is at the outer end of the backing support, because if the hinges are placed on either side, the flow of the sample solution can be different on different sides of the layers. When the pretreatment layers and the test strip are assembled the lid is snapped over the pretreatment portion.

The layers in the pretreatment system comprises at least two different layers, which allow physical as well as chemical pretreatment of the sample. Said physical treatment means, including separation or removal of certain components or particles or means for regulating the mobility of the components in the sample solution. In order to enable the physical treatment filters (membranes) with different pore sizes or with shaped pores are used. Alternatively, filters having different so called V-pores, i.e. having pores with different diameters on each side of the filter or filters having different pore sizes on each side are used for increasing or decreasing the mobility of components in the sample solution.

The layers in the pretreatment portion can in addition to physical treatment comprise means for chemical treatment of the sample. Said chemical treatment means that the filters can contain certain compounds or compositions acting as agglutinating, coagulating, lytic, buffering and ionic strength regulating as well as immunocapturing agents. The layers can also be used as carriers for so called labels or markers, including coloured or fluorescent latex particles, gold sols, liposomes, etc. It is also possible to add chemical substance, which are capable of releasing specific components in the substances which are to be determined.

The test device comprises a supporting back prepared by a material, preferably a good quality plastic material, such as polypropens. Because of the hinges or pivots it is essential that the material is substantially non-brittle. Furthermore, the material should not contain any disturbing chemicals. It is for example not recommendable to use mold releasing agents or plasticizers when preparing the lid and support. Neither are any surface treatments recommendable.

The supporting back is provided with a lid made of the same material as the supporting back, which covers the pretreatment portion and simultaneously fixes the test strip in contact with the pretreatment layers in such a way that it enables the capillary flow of a sample solution, which has passed all the required layers into the test strip. The supporting back and the lid of the test device acts as a protector for the test stick during storage and transport.

The inside of the lid as well as the pretreatment portion of the test device is provided with means for including protrusions, pegs or tags and ridges or ribs, which fix the layers of the pretreatment portion firmly with the test strip. The contact between the test strip and the pretreated sample solution is made feasible only through the aperture allowing capillary flow from the filters to the test strip.

The lid is constructed to enable a firm capillary flow contact between the sample solution and the test strip through the filters, furthermore in the desired predetermined order. The pretreated sample solution is only absorbed through the filter layers into the test strip.

The test strip can be placed into the test device during the manufacture and sold as a ready to use disposable kit. Alternatively, the test strip, test device and layers for the pretreatment portion can be sold separately and assembled in desired manner before use.

The sample can be whole blood, serum, urine, feces, saliva, sputum, synovial fluid, amniotic fluid, but also environmental samples of different forms. Generally it is essentially that particular material can be removed from the sample. This can be achieved with filtering means such as a pad with suitable pore sizes. Sometimes the sample has to be chemically treated in order to separate interfering or disturbing components. Sometimes some specific or active components in substance to be determined from the sample have to be released before it can be determined, such are for example epitopes or active sites in certain proteins and antigens or antibodies.

The test device is preferable used with samples requiring different kinds of pretreatments. In close contact with the test strip, the lid-provided portion of the test device may contain one layer of material, or several layers of the same material or of different types of materials. These materials can e.g. have different pore sizes, and be used as prefilters. They can be impregnated with different kinds of reagents, and act as reagent layers or as immunocapture layers. These layers may be used separately or in combination with each other.

The specimen being whole blood, a separation of blood cells is usually needed. This can be achieved by preferable using two layers of material in close contact with the lateral flow test strip. The upper layer is preferably acting as a sample pad.

The sample pad together with the underlaying filter separates blood cells from whole blood allowing plasma or sera to migrate forward to the test strip.

The specimen being serum, that is prone to contain e.g. rheumatoid factors, HAMAs (Heterophilic anti-mouse antibodies), HAAAs (Heterophilic anti-animal antibodies) or the like, the lid-provided portion may contain layers impregnated with reagents for elimination of these interferences. Alternatively, the serum specimen can be applied to a layer acting as a sample pad, an eluted with a buffer containing such reagents.

The specimen being urine or a suspension of feces, the lid-provided portion may contain one or more layers of filters with the same of with different pore sizes. A prefilter with a coarse pore structure may lay on the top of one with a fine pore structure. Large and small particles can be filtered away before the sample liquid reaches the test strip.

The specimen being a urine sample with a very low pH value (caused by e.g. a preservative) or with a very low ionic strength, it may preferably be pretreated in one or several buffered layers before the sample liquid reaches the test strip.

The specimen being saliva, sputum, synovial fluid or amniotic fluid it may be preferable to use mucous releasing agents impregnated into the layers of the pretreatment portion.

The sample is added to the test device through the aperture in the lid of the pretreatment portion. The volume of the sample can be such, that no additional reagent solution is needed. In cases where the sample volume is very small, a dilution buffer is needed in order to get a flow of liquid from the pretreatment portion to the end of the test strip in the device.

The addition of sample liquid to the opening in the lid is preferable added drop-wise. The first drop of liquid spreads through the top layer of the filters, i.e. the sample pad. The further drops flow through the sample pad into the underlaying filter layer as well as spread horizontally into the back compartment of the lid portion. The filter portion are all in close contact with each other, and with the filter part of the test strip.The filter parts are laying on taps in the plastic device, and they are held in place by ribs and taps in such a way, that the liquid flows through the filter layers, and not along the inner surface of the plastic device.

The sample liquid spreads along the underlaying filter, and wets the end of the test strip, i.e. the conjugate pad. The back compartment of the lid portion is getting empty as the liquid flows forward along the conjugate pad by capillary force, and further into the membrane part of the test strip.

Conjugated microspheres dried upon the conjugate pad redissolve, and migrate forward with the liquid front into the reaction area on the membrane of the test strip. The absorbent pad in contact with the membrane absorbs excess liquid.

The sample is preferably pipetted into the hole or aperture on the cover (lid) of the test device and optionally a suitable buffer solution is added as carrier for the sample solution which drives the sample through the layers.

The solution is forced through a first filter layer which removes greater components or particles into the following layer. Behind the layers is a compartment into which redundant sample solution can be collected so that it is not forced beside and over the layers into contact with the test membrane. Furthermore, the sides of the backing support and the lid is provided with flanks, which prevent the sample solution from passing the sides of the filters. Furthermore the lid and support is provide with means for attaching the different layers in fixed positions. These means for

attaching can be provided in form of a grid lattice or more preferably in the form of pegs or tags. The lid and the backing support is also provided with a ridge or rib, which enables that only the test strip and the last filter layer are in capillary contact with one another.

Thereafter, the test is allowed to develop without any possibly disturbing movements until the result is visible. The result is recorded directly, e.g. visually from the test stick protruding above the stopper of the perforating analytical test device according to the invention. It is preferable that the amount of sample and buffer diluent is such that no solution is left in the collecting compartment.

The device of the present invention and the use thereof for performing analyses with a test stick is described in more detail by referring to the attached Figures 1-10, wherein the reference numbers and/or letters used refer to the corresponding features independent of the design of the perforating analytical test device.

In this connection it should be understood that the following description and figures are intended to be examples, which should in no way restrict the invention to the specific features shown in the figures. On the contrary, the scope of protection is intended to cover all modifications, equivalencies or alternatives, which contain the characteristics of the device as defined in the claims.

Fig. 1 is a side view of a lid-provided backing support (1) with an edge (1) and the lid (2) snapped in place to protect the layers in the pretreatment system. The backing support and the lid portion are connected with suitable fastening means, such as hinges (A) or pivots placed in the rear of the test device in the most preferred embodiment of the present invention.

Fig. 2 is a schematic picture of closed lid (2) snapped on

the backing support (1) and with the pretreatment layers (not shown) hidden under the lid and the test strip (5) fixed in their correct position. In the lid (2) is a shaped aperture (3) into which the sample solution and a possible diluent or driving solution can be added.

Fig. 3 is a sectional side-view of the lid-provided backing support (1) with the lid (2) open. The aperture (3) for adding the sample solution is shown as an intersection and two pretreatment layers (4), which include for example a first pad (4.1) and a second filter (4.2) and the test strip (5) are schematically shown as well as the fastening means or hinge (A) in the rear of the test device. The area in which the filter (4.2) is in capillary flow contact with test strip (5) is indicated with the letter (B) and the means for snapping the lid over the pretreatment portion is indicated with (C). Also shown is some tags (7) or ribs (7) which support the layers in the pretreatment portion and form a compartment (6) or reservoir basin for excess or redundant fluid.

Fig. 4 is a view seen from above of the lid-provided backing support (1) with the lid (2) open and the aperture (3) with the pretreatment layers (4) and the test strip (5) placed in the correct positions. Some ribs (7) forming the reservoir compartment (6) as well as the side wall protrusions or flank supports (8) preventing excess fluid from passing around the filters are also indicated. The fastening means or hinge (A) and filter layer-test strip-connecting area (B) as well as the snapping means (C) are schematically shown.

Fig. 5 is a sectional side view of the lid-provided backing support (1) with the lid snapped on the backing support and covering and protecting the layers (4) in the pretreatment system and connected with the test strip (5), all placed in their correct positions. The fastening means or hinge (A) and the connection area (B) between the filter (4.2) and test strip (5) as well as the snapping region (C) are also schematically shown.

Fig. 6 depicts a view seen from above of with a closed transparent lid (2). Also seen are the layers (4) of which 4.1 is a prefiltering pad and the filter (4.2) connected with the test strip (5). Two side wall protrusions and/or flanking supports (8) are also shown on each side of the filter layers. The area marked (B,C) indicates the filter-test strip connecting area as well as the snapping area.

Fig. 7 is a cross-sectional side view seen from one side in longitudinal direction of the lid-provided backing support (casing) with the lid portion (1) open and without pretreatment layers and test strip. The lid portion (1) is attached to the backing support (2) with hinges (A), which preferably are placed in the rear of the backing support (1) and not on either side of the backing support in order to avoid uneven mobility or flow of the sample fluid. The backing support comprises two portions. The lid portion being the sample pretreatment portion (2) is covered by the lid and the assay portion carries the test strip (not shown). The lid (1) is provided with a shaped aperture (3), a side wall in the backing support (1) the inside of which is shown in this figure. The lid (1) also comprises a rib (7) and taps (7) which act as fastening and supporting means for the layers (4) and the test strip (5). The lid (2) is snapped to the backing support (1) and the tags (7) which can be of different heights and breadths can be used to fix the filtering layers. They can also be placed so that they form a separate compartment (6) for collecting excess or redundant sample fluid and enable an even flow into the test strip (5) or test membrane.

In the backing support (1) in its lid portion, is also provided with taps (7) and ribs (7) of different heights which are adjusted so that they support differently shaped and sized filter layers. The filter layers are of different thickness and different sizes (dimensions). The compartment (6) act as a reservoir basin for redundant or excess sample fluid.

Fig. 8 is a schematic picture viewed from above of the lid-provided backing support (1) with the lid (2) open without pretreatment layers and test strip. The lid (2) and the supporting back or housing (1) are connected by the fastening means or hinge (A). In the lid (2) the aperture (3) is a shaped hole into which the sample is added or pipetted. The lid (2) is further provided with side wall protrusion or flank supports (8), ribs (7) and tags or pegs (7). The ribs (7) in the lid and the lid portion of the backing support forms a compartment (6) acting as a reservoir for redundant or excess sample solution. The ribs or ridges (7) are longer taps (7) and are separating the reservoir of sample solution from the test strip and forces the fluid to pass the appropriate filter layers (not shown). Some tags (7) of different height are keeping the different filter layers in desired places.

Fig. 9 is a sectional side view of the lid-provided backing support (1) with the lid (2) closed without pretreatment layers and test strip. The aperture (3) in the lid (2) is shaped to divert the sample and eluting buffer into the filter layers (not shown). Ridges or ribs (7) and taps (7) which fix the position of the filters are shown. The side wall (1.1) of the backing support (1) is shown from its inside.

Fig. 10 depicts the test device seen from above and with a transparent closed lid (2) snapped by snapping means (C) on the backing support (1) and without the pretreatment layers and the test strip. The hinges (A) are placed in the rear of the test device in the preferred embodiment of the present invention. The aperture (3) as well as supporting and fixing ribs (7) and tags (7) can be placed for example as indicated. The ribs (7) forms a compartment (6) for excess or redundant sample solution. The snapping area (7) is indicated.

EXAMPLE 1

A rapid test for screening the risk of development of iron

deficiency anemia (IDA) during pregnancy from whole blood

Serum ferritin concentration indicates the level of iron stores of the body. Ferritin is an early marker of IDA because its concentration decreases before anemia has developed. Prelatent and latent anemia can be detected before a decrease in hemoglobin concentration can be seen.

During pregnancy, serum ferritin decreases towards term. Assessment of ferritin during the first trimester of pregnancy can be used to predict the risk of development of IDA later during the pregnancy.

The rapid test for ferritin can be used to estimate the need for iron therapy during the pregnancy. The test is performed on whole blood. The cut-off value is about 40 (g/l (calibrated against WHO 3rd International Standard, code 94/572). A positive test result indicates, that the risk of developing IDA later in pregnancy is small, and no iron therapy should be needed. A negative test result indicates, that the risk of developing IDA is big, and therefore iron therapy should be recommended.

The test is based on lateral flow immunochromatography using monoclonal antibodies against human ferritin. One antibody is bound to colored microspheres, and another antibody is dispensed onto a membrane solid phase.

The test device is composed of a lateral flow test strip and filters for separation of red blood cells from whole blood mounted in the lid-provided pretreatment portion.

The test device is assembled so that at first the test strip is placed into the plastic device, then the filter layers are mounted into their places, and finally the lid is closed. The test device is packed into aluminium foil pouches together with silica gel bags.

Test performance

10 (l of whole blood is pipetted into the aperture of the lid followed by 3 drops of elution buffer. Red blood cells are retained by the filters while plasma migrates further and flows along the test strip by capillary force. The test result is read visually or by a reader 5 minutes after addition of elution buffer. One line (control line) in the test window indicates a negative test result. Two lines (test line and control line) in the test window indicate a positive result.

EXAMPLE 2

Samples for environmental fungal analysis, e.g. analysis for Stachybotrys chartarum, are collected from suitable sites identified by the investigator as representing the contaminated area sufficiently. The sample is taken from a site including building material, other substrate, accumulated dust etc. The sample is transferred into a test tube containing buffer solution and shaken carefully. The sample suspension is then transferred into a test device. The test device consists of a immunochromatographic test stick for recognizing Stachybotrys chartarum and a pretreatment device. The lid-provided pretreatment device is assembled by placing two pads of porous material in the plastic compartment. The first pad is impregnated with reagents that are capable of releasing antigenic cell components present in the fungal cell wall. The second pad is made of filtering material capable of removing large particles of fungal structure. If necessary, one more pad can be added, containing immobilized antibodies that capture components that might cause nonspecific reactions with the antibodies used in the immunochromatographic test stick.Sample suspension in buffer is pipetted into the aperture in the lid. Within 5 minutes, the sample liquid will migrate through the pads for pretreatment, and along the test strip. If there is any fungal antigen present, a visible line will form in the test strip and the test can be interpreted as positive, that is, the site to be inspected is contaminated by

the fungus in case. Samples for environmental fungal analysis, eg analysis for Stachybotrys chartarum, are collected from suitable sites identified by the investigator as representing the contaminated area sufficiently. The sample is taken from a site including building material, other substrate, accumulated dust etc. The sample is transferred into a test tube containing buffer solution and shaken carefully. The sample suspension is then transferred into a test device. The test device consists of a immunochromatographic test stick for recognizing Stachybotrys chartarum and a pretreatment device. The lid-provided pretreatment device is assembled by placing two pads of porous material in the plastic compartment. The first pad is impregnated with reagents that are capable of releasing antigenic cell components present in the fungal cell wall. The second pad is made of filtering material capable of removing large particles of fungal structure. If necessary, one more pad can be added, containing immobilized antibodies that capture components that might cause nonspecific reactions with the antibodies used in the immunochromatographic test stick.Sample suspension in buffer is pipetted into the aperture in the lid. Within 5 minutes, the sample liquid will migrate through the pads for pretreatment, and along the test strip. If there is any fungal antigen present, a visible line will form in the test strip and the test can be interpreted as positive, that is, the site to be inspected is contaminated by the fungus in case.

Claims:

1. A test device with a sample pretreating portion for performing assays, c h a r a c t e r i z e d in, that the test device comprises on a test-strip backing support (1) a pretreatment portion provided with a lid (2) with an aperture (3), said lid covering and protecting a pretreatment system having at least two layers (4) horizontally stapled upon each other and assembled in a capillary flow connection with a test strip (5) placed on the lid-provided backing support, the positions of the layers of the pretreatment system and the test strip being fixed with said lid.

2. The test device according to claim 1, c h a r a c t e r i z e d in, that the pretreatment system comprises at least two layers (4) providing physical and/or chemical means for pretreating the sample.

3. The test device according to claim 2, c h a r a c t e r i z e d in, that the physical means for separating and/or removing components from the sample solution are provided by filter layers with variable thickness and size, each layer having pores with different diameters and/or shaped pores.

4. The test device according to claim 2, c h a r a c t e r i z e d in, that the physical means for regulating the motility of components in the sample solution or regulating reaction velocities are provided by one or more filter layers having shaped pores with different diameters on each side of the filter layer.

5. The test device according to claim 1, c h a r a c t e r i z e d in, that the chemical means for treating the sample solution comprise buffering, ionic strength regulating, agglutinating, coagulating and/or lytic agents as well as catalyzators, labels, markers, substrates and/or reagents.

6. The test device according to claim 1, c h a r a c t e r i z e d in, that the backing support (1) and the lid (2), which keep the layers (4) in the pretreatment system in their correct positions and connect them with the test strip (5) are provided with means for securing and fixing the position of the layers, regulating the flow of the sample solution, and for forming a compartment (6) for collecting excess sample fluid in order to enable an even passage through each layer in a predetermined order and subsequently into the test strip (5).

7. The test device according to claim 1, c h a r a c t e r i z e d in, that it comprise tabs (7) or longer ribs (7) and flanking supports (8) of different heights and sizes in order to keep the layers in their correct positions.

8. The test device according to claim 1, c h a r a c t e r i z e d in, that it comprise ones or more tabs (7) which support and fix the pretreatment layers (4) so that the sample solution flows through the layers (4) in predetermined order and thereafter into the test strip (5) by capillary flow.

9. The test device according to claim 1, c h a r a c t e r i z e d in, that it comprises at least two side wall protrusions providing flanking supports (8) preventing the layers from moving in side direction and simultaneously forcing the sample solution to move through the layers in predetermined order.

10. The test device according to claim 1, c h a r a c t e r i z e d in, that it comprises at least one rib (7), which forms an empty compartment for collecting excess sample solution.

11. A method for carrying out a rapid bed-side test without pretreating the sample, c h a r a c t e r i z e d in, that the sample is added into the aperture (3) in the lid (2) on the backing support (1) of the test device and a diluent or driving solution is added which is capable of driving the sample solution through the layers in the pretreatment system, wherein particles are captured and interfering substances are removed or allowed to react by using the physical or chemical means in the layers of the pretreatment system and collecting the superfluous fluid in a compartment to enable an even flow into the test strip where the result is readable as one or more zones.

Abstract

The present invention is related a test device with a lid-provided pretreatment portion mounted on the same backing support as a test strip as well as method for pretreating the sample fluid without the need of a separate and time consuming pretreatment procedure of the sample solution. The test device and method are especially useful for rapid bed-side assay e.g. in emergency situations such as those encountered in ambulances.

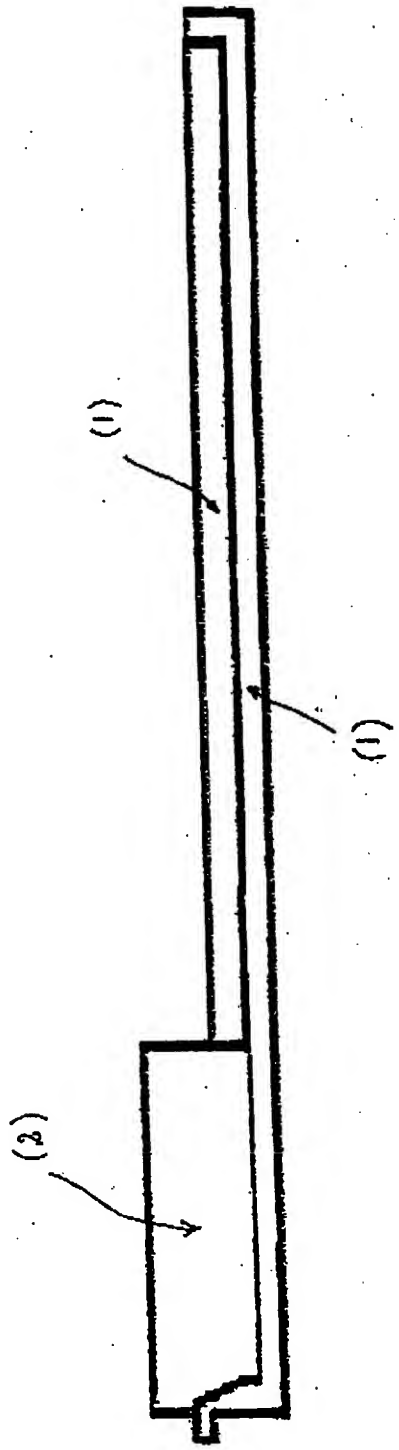

FIG. 1

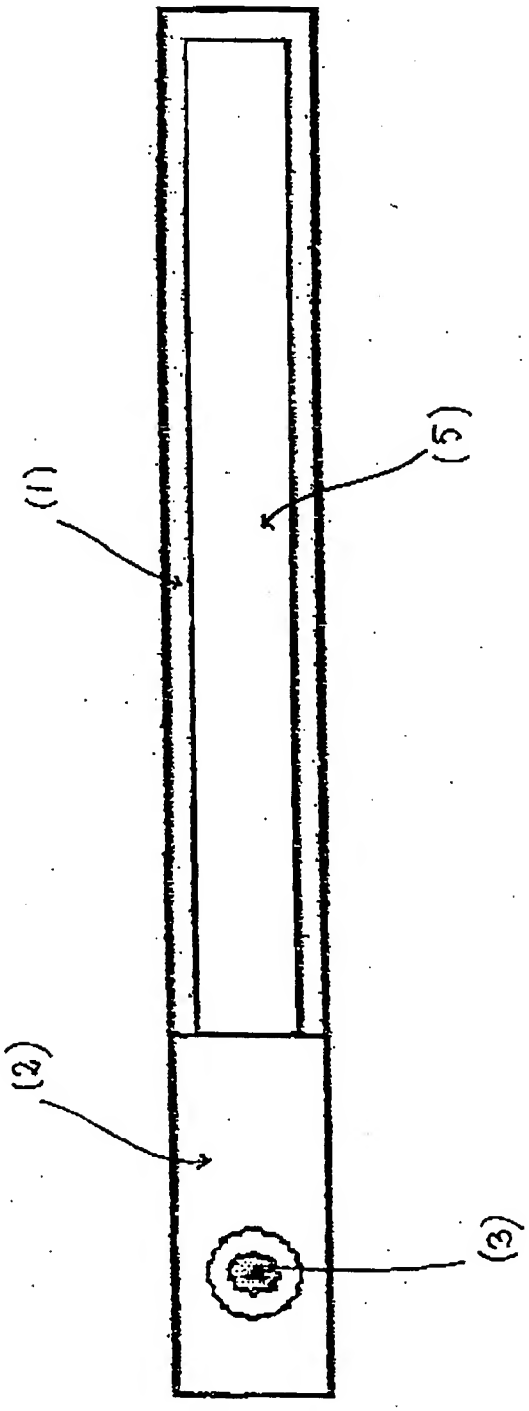

FIG. 2

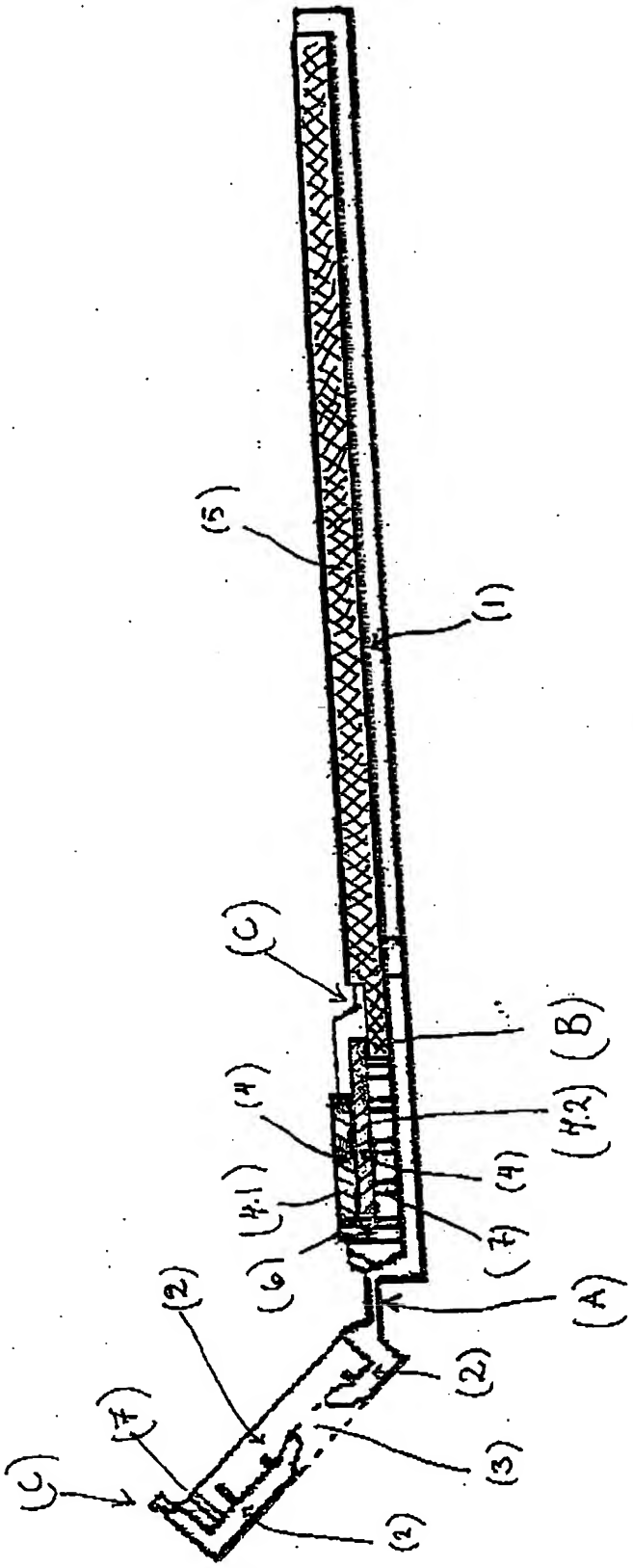

FIG. 3

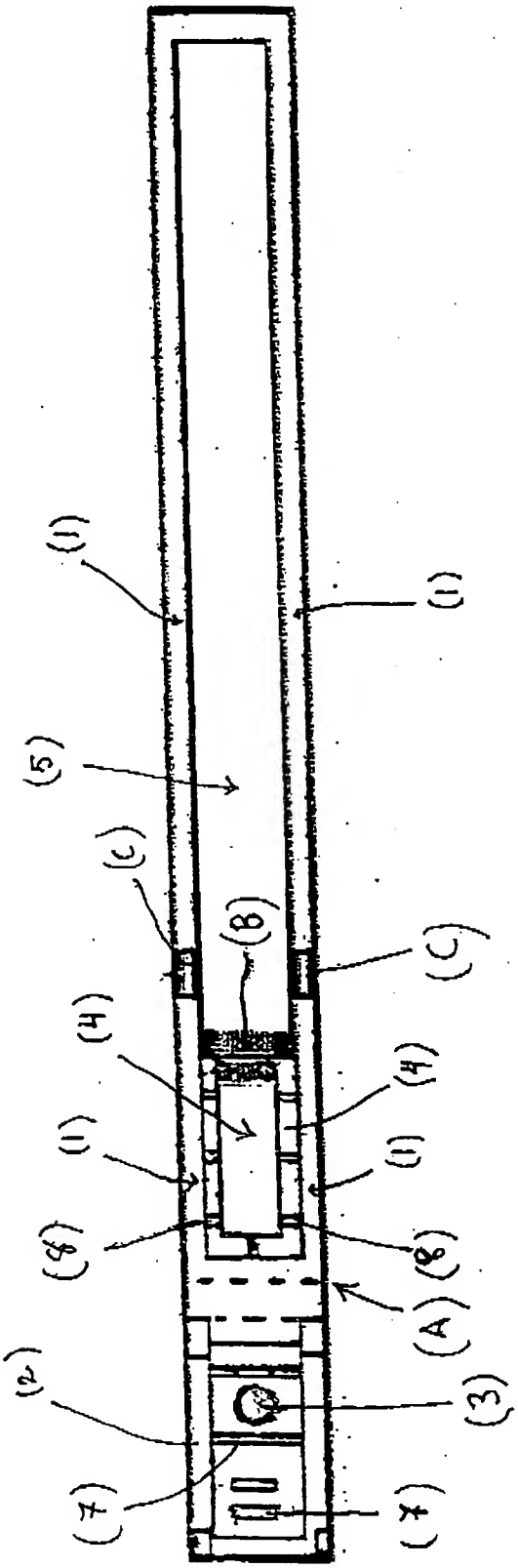

FIG. 4

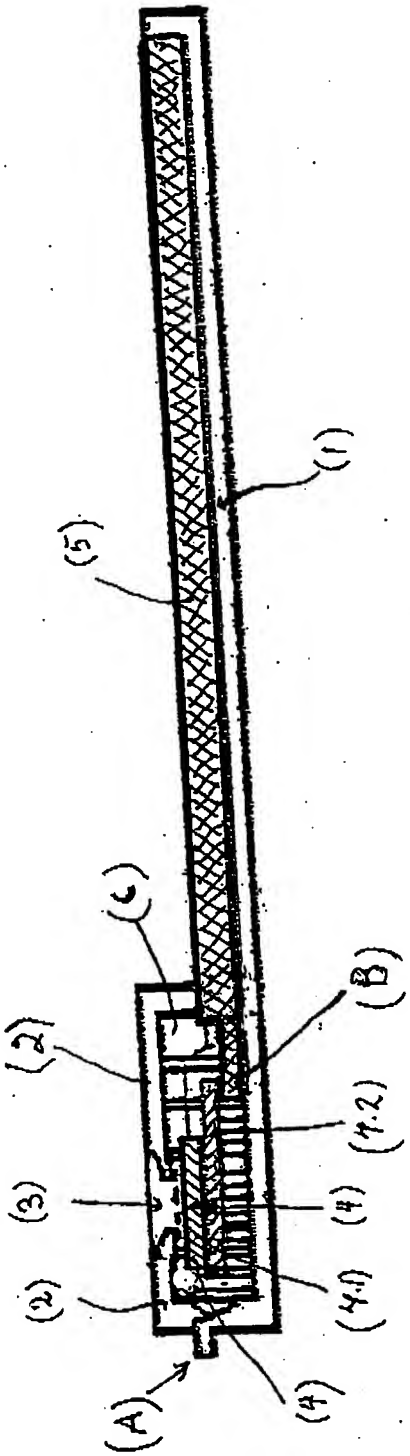

FIG. 5

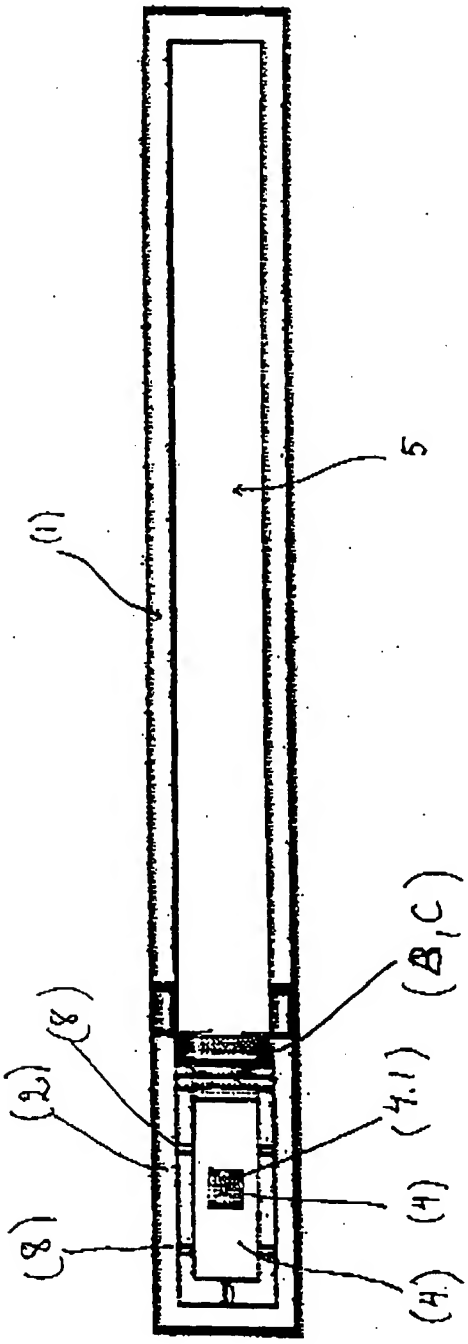

FIG. 6

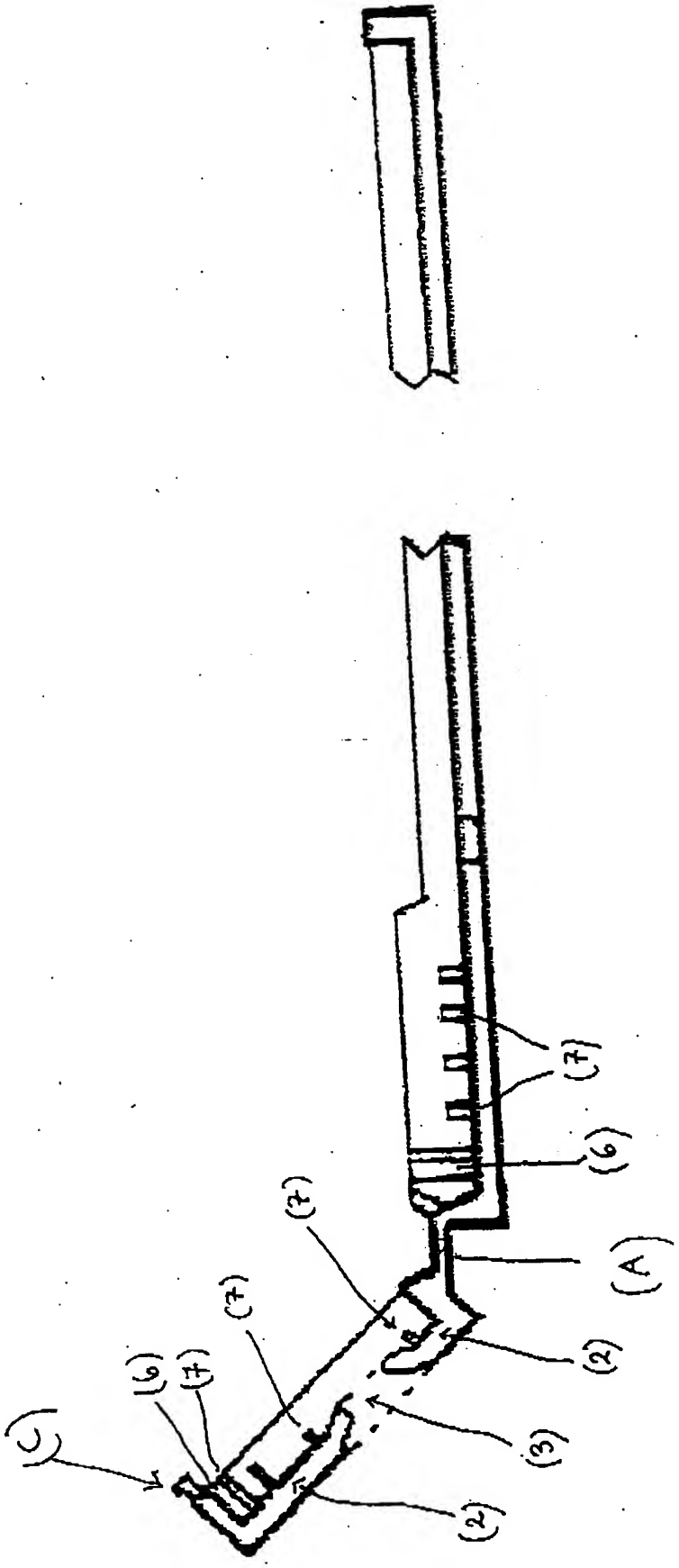

FIG. 7